

AUG 17 2005

### 510(k) Summary for Stratus® CS D-Dimer Assay

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K051597

**1. Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation:**

Manufacturer: Dade Behring Inc.  
Glasgow Site  
P.O. Box 6101  
Newark, Delaware 19714

Contact Information: Attn: Kathleen Dray-Lyons  
Tel: 781-826-4551  
Fax: 781-826-2497  
E-mail: [kathleen\\_dray-lyons@dadebehring.com](mailto:kathleen_dray-lyons@dadebehring.com)

Preparation date: June 15, 2005

**2. Device Name/ Classification:** Stratus® CS D-Dimer Assay  
**Class:** Fibrinogen and Fibrin Split Product, Class II,  
21 CFR 864.7320  
**Panel:** Hematology (HE)  
**Product Code:** DAP

**3. Identification of the Legally Marketed Device:**

Stratus® CS D-Dimer (DDMR) Assay (K022976)

**4. Device Description:**

The Stratus® CS DDMR procedure is a two-site sandwich assay based upon solid phase Radial Partition Immunoassay (RPIA) technology. In this procedure, dendrimer linked monoclonal antibody is added to the center portion of a square piece of glass fiber paper in the DDMR TestPak. This antibody recognizes a distinct antigenic site on the D-dimer molecule. Sample is then added onto the paper where it reacts with the immobilized antibody. After a short incubation, a conjugate consisting of enzyme-labeled monoclonal antibody directed against a second distinct antigenic site on the D-dimer molecule is pipetted onto the reaction zone of the paper. During this second incubation period, enzyme-labeled antibody reacts with the bound D-dimer, forming an antibody-antigen-labeled antibody sandwich. The unbound labeled antibody is later eluted from the field of view of the Stratus® CS analyzer by applying a substrate wash solution to the center of the reaction zone. By including substrate for the enzyme within the wash solution, initiation of enzyme activity occurs simultaneously with the wash. The enzymatic rate of the bound fraction increases directly with the concentration of D-dimer in the sample. The reaction rate can then be measured by an optical system that monitors the reaction rate via front surface fluorescence. All data analysis functions are performed by the microprocessor within the analyzer.

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**5. Device Intended Use:**

The D-dimer (DDMR) method on the Stratus® CS STAT fluorometric analyzer is an *in vitro* diagnostic test for the quantitative measurement of cross-linked fibrin degradation products (D-dimer) in human citrated or heparinized plasma. The Stratus® CS DDMR method is intended for use as an aid in the diagnosis of venous thromboembolism (VTE) [deep vein thrombosis (DVT) or pulmonary embolism (PE)].

**6. Medical device to which equivalence is claimed and comparison information:**

The modified Stratus® CS D-Dimer assay is substantially equivalent to the Stratus® CS D-Dimer currently marketed (K022976). The modified assay, like the current Stratus® CS D-Dimer, is intended for the quantitative determination of cross-linked fibrin degradation products containing D-dimer in human citrated or heparinized plasma for use with the Stratus® CS STAT fluorometric analyzer.

**7. Device Performance Characteristics:**

**Stratus® CS D-Dimer Clinical Study Summary**

<b>VTE Patients</b>	<b>Cutoff ng/mL</b>	<b>Sensitivity (%)</b>	<b>Specificity (%)</b>	<b>NPV (%)</b>
832	450	94	52	95



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Ms. Kathleen A. Dray-Lyons  
Regulatory Affairs and Compliance Manager  
Dade Behring, Inc.  
Glasgow Site  
P.O. Box 6101  
Newark, Delaware 19714

**AUG 17 2005**

Re: k051597  
Trade/Device Name: Stratus® CS D-Dimer (DDMR) Assay  
Regulation Number: 21 CFR § 864.7320  
Regulation Name: Fibrinogen/fibrin degradation products assay  
Regulatory Class: II  
Product Code: DAP  
Dated: June 15, 2005  
Received: June 16, 2005

Dear Ms. Dray-Lyons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,

A handwritten signature in black ink, reading "Robert L. Becker, Jr." with a stylized flourish at the end.

Robert L. Becker, Jr., MD, Ph.D

Director

Division of Immunology and Hematology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

### Indications Statement

K051597

Device Name: Stratus® CS D-Dimer (DDMR) Assay

#### Indications for Use:


The D-dimer (DDMR) method on the Stratus® CS STAT fluorometric analyzer is an *in vitro* diagnostic test for the quantitative measurement of cross-linked fibrin degradation products (D-dimer) in human citrated or heparinized plasma. The Stratus® CS DDMR method is intended for use as an aid in the diagnosis of venous thromboembolism (VTE) [deep vein thrombosis (DVT) or pulmonary embolism (PE)].

Prescription Use ☒  
(Per 21 CFR 801 Subpart D)

Over-The-Counter-Use \_\_\_\_\_  
(21 CFR 801)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

  
Division Sign-Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) K051597

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